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## **A new policy to implement CONSORT guidelines for surgical randomized controlled trials**

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# A New Policy to Implement CONSORT Guidelines for Surgical Randomized Controlled Trials

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**R**igorously designed, conducted, and analyzed randomized controlled trials (RCTs) represent the gold standard in evaluating surgical interventions. If they are also reported completely and transparently, this can lead to level 1 evidence.<sup>1</sup> However, RCTs need methodological rigor and complete reporting to be conclusive. To assess a trial accurately, readers of a published report need sufficient, easily understandable, and transparent information on the methodology used. Knowledge about the methodological accuracy and the relevant results of a trial can only be assessed if reporting follows standardized methods. A systematic review of surgical RCTs published in this Journal indicated that the study design was reported with sufficient detail in less than 40% of the articles.<sup>2</sup> Although also incomplete in many studies, the quality of reporting seemed better for pharmacological trials than for surgical trials.<sup>3</sup>

The need for guidelines was recognized in the early 1990s to overcome these shortcomings, which led to the development of the original CONSORT (Consolidated Standards of Reporting Trials) Statement in 1996,<sup>4</sup> followed by 2 revisions, most recently in 2010.<sup>5,6</sup> Although the implementation of CONSORT guidelines undoubtedly improved the reporting quality for many RCTs, other reports, including most surgical trials, remained grossly inadequate.<sup>6</sup> Although CONSORT guidelines are aimed at any types of RCTs, the focus was on the most common design type, that is, randomized, 2-group, and parallel trials.<sup>6</sup> A further development, relevant for the surgical field, was the initiation of the CONSORT extension targeting nonpharmacological trials (NPTs) covering a wide range of interventions including surgical procedures or other interventions such as angioplasty or implantable and nonimplantable medical devices.<sup>6,7</sup> The CONSORT NPT statement takes into consideration specific issues when assessing a variety of interventions, such as difficulties of blinding, the complexity of the intervention, the influence of care providers' expertise, the volume of case at participating centers, and other factors affecting the treatment effects. For example, the CONSORT flow diagram was modified to include data on the number of care providers and centers in each group and the number of patients treated by each care provider.<sup>7</sup>

Despite these efforts, compliance with the CONSORT checklist has remained poor. It is possible that endorsement is not optimal because some authors perceive the 25-item checklist as a barrier to complying with the CONSORT recommendations. This concern led to a retreat of the CONSORT NPT group in May 2014 in the beautiful Château d'Ermenonville, France, which included epidemiologists, trialists, statisticians, journal and publisher representatives, and a few surgeons. The main topic was how to enhance adherence of authors and journals to the CONSORT NPT guidelines. The group agreed to a 2-step implementation of the guidelines, starting with a first step requiring the completion of a 10-item CONSORT NPT checklist, called the CONSORT NPT "submission" checklist, to be provided upon submission of any surgical RCT, followed by the whole CONSORT NPT checklist<sup>6</sup> to be completed after provisional acceptance by the journal; that is, this information will not influence the decision of whether or not to accept a manuscript for publication.

Making the CONSORT NPT submission checklist mandatory for submission is meant to guarantee sufficient critical information to enable proper understanding and evaluation of the trial. We hope that the reduced 10-item checklist will make it easier for authors to comply with the journal's implementation of CONSORT NPT. Use of CONSORT is associated with more completely reported RCTs.<sup>8</sup> The group of surgeons and NPT CONSORT group leaders, listed later, selected 10 key items, all from the CONSORT NPT checklist, which are readily available to any prospective authors. These items are presented, with examples and short explanations, to facilitate understanding and implementation by surgeons (see the Supplemental Table and Flow sheet, available at ...). The

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whole CONSORT NPT checklist will have to be provided only for the accepted RCTs and will be published online along with the article in compliance with the CONSORT NPT checklist.

*Annals of Surgery*, as one of the leading journals in surgery, will implement this policy for all submissions beginning January 2015. Thus, the CONSORT NPT *submission* checklist will have to be completed online upon submission of any RCT. If the manuscript is provisionally accepted for publication, the whole CONSORT checklist will be required at the time the revised manuscript is submitted but without impact on the decision to publish the manuscript. We hope that this new policy will enable better reporting of RCTs and facilitate further interpretation in the setting of other results and even facilitate meta-analyses.

Similar to RCTs, adherence to reporting guidelines is critical for interpreting meta-analyses or systematic reviews. *Annals of Surgery* strongly encourages prospective authors to complete the PRISMA (Preferred Reporting Items of Systematic reviews and Meta-Analyses) checklist when submitting meta-analyses or systematic reviews. The PRISMA guideline was proposed in 2009<sup>9</sup> as an update of the initial QUOROM (Quality Of Reporting Of Meta-analyses) checklist, designed to describe meta-analyses.<sup>10</sup> PRISMA is an evidence-based minimum set of 27 items for reporting systematic reviews and meta-analyses, which is part of a broader effort to improve the reporting of different types of health research and, in turn, to improve the quality of research used in decision making in health care.

In summary, we are introducing the CONSORT NPT *submission* checklist consisting of 10 items to be completed upon submission of any RCTs. The items with examples are readily available online along with the submission process to *Annals of Surgery*. A flow diagram, prepared by the CONSORT group, is also provided to facilitate the implementation of this new policy. The whole CONSORT NPT checklist will be provided after provisional acceptance and before publication.

### SPECIAL NOTE

The CONSORT NPT *submission* checklist was developed by the participating surgeons at the NPT CONSORT retreat: Peter

McCulloch, Oxford, UK, Markus, Diener, Heidelberg, Germany, Ksenija Slankamenac, Zurich, Switzerland, and Pierre A. Clavien, Zurich, Switzerland, with the input of the chairs of the CONSORT NPT group, Isabelle Boutron and Philippe Ravaut, and CONSORT leaders, Doug Altman, Ken Schulz, and David Moher.

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